

CLAIMS

1. An orally disintegrable tablet which comprises (i) fine granules having an average particle diameter of 400 μm or less, which fine granules comprise a composition coated by an enteric coating layer, said composition having 10 weight % or more of an acid-labile physiologically active substance and (ii) an additive.

2. An orally disintegrable tablet of claim 1, wherein the average particle diameter of the fine granules is 300 to 400 μm .

3. An orally disintegrable tablet of claim 1, wherein the fine granules further comprise a basic inorganic salt.

4. An orally disintegrable tablet of claim 1, wherein the additive comprises a water-soluble sugar alcohol.

5. An orally disintegrable tablet of claim 1, wherein the composition coated by an enteric coating layer is further coated by a coating layer which comprises a water-soluble sugar alcohol.

6. An orally disintegrable tablet of claim 4, wherein the additive comprises (i) crystalline cellulose and/or (ii) low-substituted hydroxypropyl cellulose.

7. An orally disintegrable tablet of claim 1, wherein the particle diameter of the fine granules is practically 425 μm or less.

8. An orally disintegrable tablet of claim 1, wherein the particle diameter of the fine granules is practically 400 μm or less.

9. An orally disintegrable tablet of claim 1, wherein the acid-labile physiologically active substance is a benzimidazole compound or a salt thereof.

10. An orally disintegrable tablet of claim 9, wherein the benzimidazole compound is lansoprazole.

11. An orally disintegrable tablet of claim 3, wherein the basic inorganic salt is a salt of magnesium and/or a salt of calcium.

12. An orally disintegrable tablet of claim 1, wherein the composition comprises a core being coated by a benzimidazole compound and a basic inorganic salt, said core comprising crystalline cellulose and lactose.

5 13. An orally disintegrable tablet of claim 12, wherein the core comprises 50 weight % or more of lactose.

14. An orally disintegrable tablet of claim 12, wherein the core comprises 40 to 50 weight % of crystalline cellulose and 50 to 60 weight % of lactose.

10 15. An orally disintegrable tablet of claim 1, wherein the composition comprises 20 weight % or more of an acid-labile physiologically active substance.

15 16. An orally disintegrable tablet of claim 1, wherein the composition comprises 20 to 50 weight % of an acid-labile physiologically active substance.

17. An orally disintegrable tablet of claim 1, wherein the fine granules are produced by fluidized-bed granulation method.

20 18. An orally disintegrable tablet of claim 1, wherein the enteric coating layer comprises an aqueous enteric polymer agent.

19. An orally disintegrable tablet of claim 18, wherein the aqueous enteric polymer agent is a methacrylate copolymer.

25 20. An orally disintegrable tablet of claim 18, wherein the enteric coating layer further comprises a sustained-release agent.

21. An orally disintegrable tablet of claim 20, wherein the sustained-release agent is a methacrylate copolymer.

30 22. An orally disintegrable tablet of claim 20, wherein the sustained-release agent is in an amount of 5 to 15 weight % relative to 100 weight % of the aqueous enteric polymer agent.

23. An orally disintegrable tablet of claim 4, wherein the water-soluble sugar alcohol is erythritol.

35 24. An orally disintegrable tablet of claim 4, wherein the water-soluble sugar alcohol is mannitol.

25. An orally disintegrable tablet of claim 5, wherein the water-soluble sugar alcohol is in an amount of 5 to 97 weight % relative to 100 weight % of the orally disintegrable tablet apart from the fine granules.

5 26. An orally disintegrable tablet of claim 4, wherein the crystalline cellulose is in an amount of 3 to 50 weight % relative to 100 weight % of the tablet apart from the fine granule.

10 27. An orally disintegrable tablet of claim 6, wherein the content of hydroxypropoxyl group in the low-substituted hydroxypropyl cellulose is 7.0 to 9.9 weight %.

28. An orally disintegrable tablet of claim 6, wherein the content of hydroxypropoxyl group in the low-substituted hydroxypropyl cellulose is 5.0 to 7.0 weight %.

15 29. An orally disintegrable tablet of claim 1, which further comprises crospovidone.

30. An orally disintegrable tablet of claim 1, wherein the oral disintegration time is one minute or less.

20 31. An orally disintegrable tablet of claim 1, which comprises no lubricant inside the tablet.

32. Fine granules having an average particle diameter of 400 μm or less, which comprise a composition coated by an enteric coating layer, said composition having (i) 25 weight % or more of an acid-labile physiologically active substance and (ii) a basic inorganic salt.

25 33. Fine granules of claim 32, wherein the average particle diameter of the fine granules is 300 to 400 μm .

34. Fine granules of claim 32, wherein the particle diameter of the fine granules is practically 425 μm or less.

30 35. Fine granules of claim 32, wherein the particle diameter of the fine granules is practically 400 μm or less.

36. Fine granules of claim 32, wherein the acid-labile physiologically active substance is a benzimidazole compound or a salt thereof.

37. Fine granules of claim 36, wherein the benzimidazole compound is lansoprazole.

38. Fine granules of claim 32, wherein the basic inorganic salt is a salt of magnesium and/or a salt of calcium.

5 39. Fine granules of claim 32, wherein the composition comprises a core being coated by a benzimidazole compound and a basic inorganic salt, said core comprising crystalline cellulose and lactose.

10 40. Fine granules of claim 39, wherein the core comprises 50 weight % or more of lactose.

41. Fine granules of claim 32, wherein the composition comprises 25 to 40 weight % of an acid-labile physiologically active substance.

15 42. Fine granules of claim 32, which are produced by fluidized-bed granulation method.

43. Fine granules of claim 32, wherein the enteric coating layer comprises an aqueous enteric polymer agent.

44. Fine granules of claim 43, wherein the aqueous enteric polymer agent is a methacrylate copolymer.

20 45. Fine granules of claim 43, wherein the enteric coating layer further comprise a sustained-release agent.

46. Fine granules of claim 45, wherein the sustained-release agent is a methacrylate copolymer.

25 47. Fine granules of claim 45, wherein the sustained-release agent is in an amount of 5 to 15 weight % relative to 100 weight % of the aqueous enteric polymer agent.

48. Fine granules of claim 32, wherein the enteric coating layer is in an amount of 50 to 70 weight % relative to 100 weight % of the fine granules.

30 49. A tablet, granule, fine granule, capsule, effervescent or suspension preparation which comprises the fine granules of claim 32.